

INSTRUCTIONS FOR USE

Central Venous Catheter (CVC) Short Term Product (Kit / Set)

Indications:

The MEDADV® CVC provide short-term (less than 30 days) central venous access only for treatment or intravenous therapy for conditions requiring central venous access, like following (not exclusive):

- Absence of usable peripheral IV sites
- Infusions of fluids, medications, or chemotherapy
- Central venous pressure monitoring
- Total parenteral nutrition (TPN)
- Frequent blood sampling or receiving blood transfusions/blood products
- Any other consider by medical specialist.

Precautions:

1. Any alteration of catheter, guidewire kit/set accessories or components during placement, use or removal, could lead serious injuries or death.
2. **Only Rx Procedure:** performed by trained medical operators well knowledge in anatomical references, using safe placement technique and avoiding potential complications.
3. Standard precautions following established institutional, and educational procedures, must be performed.
4. Avoid use at catheter insertion site; solvents or disinfectants like: Acetone, alcohol, glycols derivatives, etc. Eventually can affect polyurethane catheter materials built. Also affect adhesive bond between catheter stabilization method used and skin.
On catheter surface, Acetone is forbidden. Do not use alcohol to drench catheter structure or allow leave in a catheters lumens to unobstructed it. Avoid use containing glycols derivatives at insertion site. Consideration must be taken using medicines or drugs with high volume of alcohol through catheter lumens.
Prior apply dressing on insertion site let complete dry.
5. Assume unobstructed catheter; instilling saline solution with a 10 ml syringe or higher, to avoiding intra lumen leaking.
6. Handle catheter properly, keep proximal and distal parts of catheter positioned following anatomical landmarks, and institutional directions for this.

Warnings and Cautions

Warnings:

1. Don't use if package is damage or open.
2. Read all package insert warnings, precautions and instructions prior to use. Omission of this warning may result in severe patient injury or death.
3. Sterile product for single use: reuse, reprocess or re-sterilize is forbidden.
4. Place catheter in correct position avoiding the right atrium or right ventricle. Using x-ray exam or fluoroscopy in must show catheter tip located at least in lower 1/3 of the Superior Vena Cava (SVC).
5. Trained operator must not use excessive force apply introducing guidewire or tissue dilator, this can lead to vessel perforation, bleeding, or device damage.
6. Trained operator must be aware of potential tangle of the guidewire by other implanted device in circulatory system boarded.
7. In case of patient has a circulatory system implant, catheter procedure be done under direct visualization to reduce risk of guidewire tangle.
8. The guidewire aboard into the right atrium can lead dysrhythmias, branch block, and a perforation, atrial or ventricular wall in case of pass through tricuspid valve.
9. Excessive force apply in placing or removing catheter or guidewire could lead device damage. If damage is suspected or withdrawal cannot be easily accomplished, radiographic visualization should be obtained and further consultation requested.
10. Read carefully pressures of lumens catheter before using high pressure injection, that can cause inter-lumen crossover or rupture with potential for injury.
11. Do not fix, by any method directly to outside diameter of catheter round hub or extension lines to reduce risk of cutting or damaging the catheter flow. Stabilize catheter only in designated area.
12. Embolism by air can occur in case air is allowed to enter in central venous access device. Keep capped, clamped needles, and catheter in central venous puncture site. Use only Luer Lock connections with any central venous access device to maintain against inadvertent disconnection.
13. Medical operators should be aware that slide clamps may be inadvertently unattached.
14. Other complications linked with central venous catheters placement (not exclusive): Catheter embolism, air embolism, Cardiac tamponade follow anatomical structure perforation, thrombosis, hematoma, hemorrhage, bacteremia, septicemia, Catheter infection site, Arrhythmia, Catheter malfunction, Obstructed catheter, Catheter kinking, Catheter tip out of position.

Kits/Sets may vary in accessories components detailed in these instructions for use. Inspect this configuration before use.

A Suggested Procedure: Use sterile technique.

Prep Puncture Site:

1. Position patient as appropriate for insertion site.
 - Subclavian or Jugular approach: Place patient in slight Trendelenburg position as tolerated to reduce risk of air embolism and enhance venous filling.
 - Femoral approach: Place patient in supine position.
2. Prepare clean skin with an appropriate antiseptic agent.
3. Drape puncture site.
3. Administer local anesthetic per institutional policies and procedures.
4. Dispose of needle.

Prepare Catheter:

5. Flush each lumen with sterile normal saline for injection to establish patency and prime lumen(s).
6. Clamp or attach Luer-Lock connector(s) to extension line(s) to contain saline within lumen(s).
7. Leave distal extension line uncapped for guidewire passage.

 **Warning: Do not cut catheter to modify length.**

MEDADV® Raulerson Syringe (where is provided):

MEDADV® Raulerson Syringe is used in conjunction with MEDADV® Advancer for guidewire insertion.

8. Insert introducer needle or catheter/needle with attached syringe or MEDADV® Raulerson Syringe (where provided) into vein and aspirate.

 **Warning: Do not leave open needles or uncapped, unclamped catheters in central venous puncture site. Air embolus can occur with these practices.**

 **Caution: Do not reinsert needle into introducer catheter (where provided) to reduce risk of catheter embolus.**

Verify Venous Access:

Utilize one of the following techniques to verify venous access because of the potential for inadvertent arterial placement:

- Central Venous Waveform:
 - Insert fluid primed blunt tip pressure transduction probe into rear of plunger and through valves of MEDADV® Raulerson Syringe and observe for central venous pressure waveform.
 - Remove transduction probe if using MEDADV® Raulerson Syringe.
- Pulsatile Flow (if hemodynamic monitoring equipment is not available):
 - Use transduction probe to open syringe valving system of MEDADV® Raulerson Syringe and observe for pulsatile flow.
 - Disconnect syringe from needle and observe for pulsatile flow.

 **Warning: Pulsatile flow is usually an indicator of inadvertent arterial puncture.**

 **Caution: Do not rely on blood aspirate color to indicate venous access.**

Insert Guidewire:

Guidewire:

Kits/Sets are available with a variety of guidewires. Guidewires are provided in different diameters, lengths and tip configurations for specific insertion techniques. Become familiar with the guidewire(s) to be used with the specific technique before beginning the actual insertion procedure.

MEDADV® Advancer (where provided):

MEDADV® Advancer is used to straighten "J" Tip of guidewire for introduction of the guidewire into MEDADV® Raulerson Syringe or a needle.

- Using thumb, retract "J" (refer to Figure 2).

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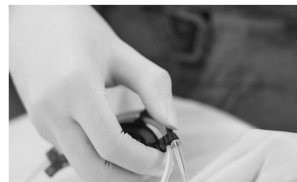


Figure 2

- Place tip of MEDADV® Advancer – with "J" retracted – into the hole in rear of MEDADV® Raulerson Syringe plunger or introducer needle (refer to Figure 3).



Figure 3

9. Advance guidewire into MEDADV® Raulerson Syringe approximately 10 cm until it passes through syringe valves or into introducer needle.
 - Advancement of guidewire through MEDADV® Raulerson Syringe may require a gentle rotating motion.
10. Raise thumb and pull MEDADV® Advancer approximately 4 - 8 cm away from MEDADV® Raulerson Syringe or introducer needle. Lower thumb onto MEDADV® Advancer and while maintaining a firm grip on guidewire, push assembly into syringe barrel to further advance guidewire. Continue until guidewire reaches desired depth.

11. Use centimeter markings (where provided) on guidewire as a reference to assist in determining how much guidewire has been inserted.

NOTE: When guidewire is used in conjunction with MEDADV® Raulerson Syringe (fully aspirated) and a 2-1/2" (6.35 cm) introducer needle, the following positioning references can be made:

- 20 cm mark (two bands) entering back of plunger = guidewire tip at end of needle
- 32 cm mark (three bands) entering back of plunger = guidewire tip approximately 10 cm beyond end of needle

⚠Caution: Maintain firm grip on guidewire at all times. Keep sufficient guidewire length exposed for handling purposes. A non-controlled guidewire can lead to wire embolus.

⚠Warning: Do not aspirate MEDADV® Raulerson Syringe while guidewire is in place; air may enter syringe through rear valve.

⚠Caution: Do not reinfuse blood to reduce risk of blood leakage from rear (cap) of syringe.

⚠Warning: Do not withdraw guidewire against needle bevel to reduce risk of possible severing or damaging of guidewire.

12. Remove introducer needle and MEDADV® Raulerson Syringe (or catheter) while holding guidewire in place.
13. Use centimeter markings on guidewire to adjust indwelling length according to desired depth of indwelling catheter placement.
14. If necessary, enlarge cutaneous puncture site with cutting edge of scalpel, positioned away from guidewire.

⚠Warning: Do not cut guidewire to alter length.

⚠Warning: Do not cut guidewire with scalpel.

- Position cutting edge of scalpel away from guidewire.
- Engage safety and/or locking feature of scalpel (where provided) when not in use to reduce the risk of sharps injury.

15. Use tissue dilator to enlarge tissue tract to the vein as required. Follow the angle of the guidewire slowly through the skin.

⚠Warning: Do not leave tissue dilator in place as an indwelling catheter. Leaving tissue dilator in place puts patient at risk for possible vessel wall perforation.

Advance Catheter:

16. Thread tip of catheter over guidewire. Sufficient guidewire length must remain exposed at hub end of catheter to maintain a firm grip on guidewire.
17. Grasping near skin, advance catheter into vein with slight twisting motion.

⚠Warning: Do not attach catheter clamp and fastener (where provided) until guidewire is removed.

18. Using centimeter marks on catheter as positioning reference points, advance catheter to final indwelling position.

NOTE: Centimeter marking symbology is referenced from catheter tip.

- numerical: 5, 15, 25, etc.
- bands: each band denotes a 10 cm interval, with one band indicating 10 cm, two bands indicating 20 cm, etc.
- dots: each dot denotes a 1 cm interval

19. Hold catheter at desired depth and remove guidewire.

⚠Caution: If resistance is encountered when attempting to remove guidewire after catheter placement, guidewire may be kinked around tip of catheter within vessel (

- In this circumstance, pulling back on guidewire may result in undue force being applied resulting in guidewire breakage.

- If resistance is encountered, withdraw catheter relative to guidewire about 2-3 cm and attempt to remove guidewire.
- If resistance is again encountered, remove guidewire and catheter simultaneously.

⚠Warning: Do not apply undue force on guidewire to reduce risk of possible breakage.

20. Always verify entire guidewire is intact upon removal.

Complete Catheter Insertion:

21. Check lumen patency by attaching a syringe to each extension line and aspirate until free flow of venous blood is observed.

22. Flush lumen(s) to completely clear blood from catheter.

23. Connect all extension line(s) to appropriate Luer-Lock connector(s) as required. Unused port(s) may be "locked" through Luer-Lock connector(s) using standard institutional policies and procedures.

- Slide clamp(s) are provided on extension lines to occlude flow through each lumen during line and Luer-Lock connector changes.

⚠Warning: Open slide clamp prior to infusion through lumen to reduce risk of damage to extension line from excessive pressure.

Secure Catheter:

24. Use a catheter stabilization device, catheter clamp and fastener, staples or sutures (where provided).
 - Use triangular juncture hub with side wings as primary suture site.
 - Use catheter clamp and fastener as a secondary suture site as necessary.

⚠Caution: Minimize catheter manipulation throughout procedure to maintain proper catheter tip position.

Catheter Stabilization Device (where provided):

A catheter stabilization device should be used in accordance with manufacturer's instructions for use.

Catheter Clamp and Fastener (where provided):

A catheter clamp and fastener are used to secure catheter when an additional securement site other than the catheter hub is required for catheter stabilization.

- After guidewire has been removed and necessary lines have been connected or locked, spread wings of rubber clamp and position on catheter making sure catheter is not moist, as required, to maintain proper tip location.
- Snap rigid fastener onto catheter clamp.
- Secure catheter clamp and fastener as a unit to patient by using either catheter stabilization device, stapling or suturing. Both catheter clamp and fastener need to be secured to reduce risk of catheter migration (refer to Figure 5).



Figure 4

25. Ensure insertion site is dry before applying dressing per manufacturer's instructions.
26. Assess catheter tip placement in compliance with institutional policies and procedures.
27. If catheter tip is malpositioned, assess and replace or reposition according to institutional policies and procedures.

Care and Maintenance:

Dressing:

Dress according to institutional policies, procedures, and practice guidelines. Change immediately if the integrity becomes compromised e.g. dressing becomes damp, soiled, loosened or no longer occlusive.

Catheter Patency:

Maintain catheter patency according to institutional policies, procedures and practice guidelines. All personnel who care for patients with central venous catheters must be knowledgeable about effective management to prolong catheter's dwell time and prevent injury.

Catheter Removal Instructions:

28. Position patient as clinically indicated to reduce risk of potential air embolus.
29. Remove dressing.
30. Release catheter and remove from catheter securement device(s).
31. Ask patient to take a breath and hold it if removing internal jugular or subclavian catheter.
32. Remove catheter by slowly pulling it parallel to skin. If resistance is met while removing catheter **STOP**

⚠ Caution: Catheter should not be forcibly removed, doing so may result in catheter breakage and embolization. Follow institutional policies and procedures for difficult to remove catheter.

33. Apply direct pressure to site until hemostasis is achieved followed by an ointment-based occlusive dressing.

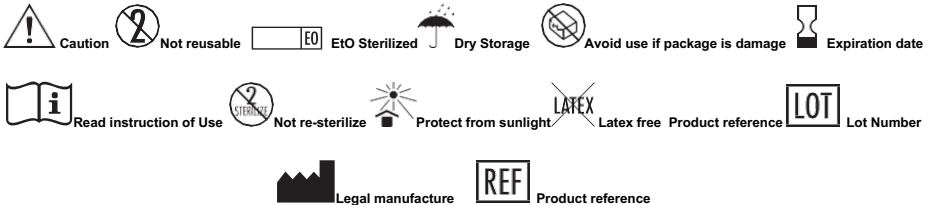
⚠ Warning: Residual catheter track remains an air entry point until site is epithelialized. Occlusive dressing should remain in place for at least 24 hours or until site appears epithelialized.

34. Document catheter removal procedure including confirmation that entire catheter length and tip has been removed per institutional policies and procedures.

For more reference literature concern; medical education, techniques, complications, etc., take counsel from medical continue education , or professional instructive media only.

MEDADV® and subsidiaries are exempted of any liability caused by incorrect use of this device and accessories.

Symbols



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